

From: Jones, Enesta [Jones.Enesta@epa.gov]
Sent: 7/19/2019 6:11:03 PM
To: Huang, Binghui [chuang@mcall.com]
CC: Press [Press@epa.gov]; White, Terri-A [White.Terri-A@epa.gov]; Nitsch, Chad [Nitsch.Chad@epa.gov]
Subject: Re: Questions regarding B. Braun and ethylene oxide

Hello Bing,

Please attribute our responses below to an EPA Spokesperson.

It looks like the reason for these high cancer risk assessments in the Lehigh Valley for cancer risks is ethylene oxide, a sterilizers used by a medical device company in the region.

I went through and looked for regulations that exists for the ethylene oxide. It looks like regulations were set in 1994. So far, reviews of the chemical has not lead to changes in regulations, is that right?

Response: EPA is taking a two-pronged approach to address ethylene oxide emissions.

1. The Agency is reviewing Clean Air Act regulations for facilities that emit ethylene oxide. EPA has begun reviewing its air toxics emissions standards for miscellaneous organic chemical manufacturing facilities, some of which emit ethylene oxide, and its air toxics rules for ethylene oxide commercial sterilizers. The agency expects to propose updates to both rules this summer.
2. EPA also is gathering additional information on industrial emissions of ethylene oxide. This information will help EPA as it evaluates opportunities to reduce ethylene oxide emissions as part of its regulations review. It also will help the Agency determine whether more immediate emission reduction steps are necessary in any particular locations.

The EPA required companies producing more than 1 ton of ethylene oxide to vent out the chemical. And facilities that produce 10 tons to have an aeration room. And these facilities are required to report emissions. These regulations don't apply to hospitals, clinics and health care providers. Is that right?

Response: EPA regulates hospital sterilizers that use ethylene oxide. Information on those regulations is available here: <https://www.epa.gov/stationary-sources-air-pollution/hospital-ethylene-oxide-sterilizers-national-emission-standards>

What does the EPA plan to do after releasing NATA data that shows the increased cancer risks of ethylene oxide emissions? What are next steps?

Response: NATA is a screening tool, intended to help EPA and state, local and tribal air agencies determine if areas, pollutants or types of pollution sources need to be examined further to better understand risks to public health. The most recent NATA identified census tracts in 18 metropolitan statistical area with potentially elevated risk from ethylene oxide. Since NATA was released, EPA has been working with its state partners and facilities to gather more refined information on ethylene oxide emissions – information that will help us in our regulations review and also will help the agency determine whether more immediate emission reduction steps are necessary in any particular location.

The EPA conducted air monitoring by Sterigenics. Does it plan to do further studies by other facilities that are major ethylene oxide emitters? Does it plan to do any monitoring or further studies by B. Braun/ in the Lehigh Valley in Pennsylvania?

Response: Outdoor air quality monitoring is not necessary for evaluating potential risk from individual facilities, There are other tools available to accomplish this work that may use resources more effectively including stack testing, reviewing permits and air dispersion modeling.

By EPA's standard, a cancer risk of more than 100 in 1 million is the standard where the agency would target emitters. In the latest NATA data, almost 64,000 people in census tracts where the risk is higher than 100 in 1 million. What does that mean for the EPA? Will there be follow up?

Response: A cancer risk level of 1-in-1 million implies that, if 1 million people are exposed to the same concentration of a pollutant continuously (24 hours per day) over 70 years (an assumed lifetime), one person would likely develop cancer from this exposure. This risk would be in addition to any cancer risk borne by a person not exposed to these air toxics.

The Clean Air Act directs EPA to regulate air toxics – which include ethylene oxide – through technology- or performance-based rules that regulate *emissions* from certain industrial facilities. Eight years after EPA sets these regulations, the law requires EPA to evaluate any remaining “residual” risks and decide whether it is necessary to control a source further. This review is where EPA uses 100-in-1 million – as a general gauge of the upper limit of acceptable risk. 100-in-1 million is not a standard or bright line above which action is required.

NATA is a screening tool, intended to help EPA and state, local and tribal air agencies determine if areas, pollutants or types of pollution sources need to be examined further to better understand risks to public health. EPA is taking a two-pronged approach to addressing ethylene oxide emissions, as noted in the question above.

On Jul 15, 2019, at 4:09 PM, Huang, Binghui <chuang@mcall.com> wrote:

Hi Ernesta,

The plan now is to publish the story online Thursday. So my deadline is Wednesday, but my editors are reading the story tomorrow, so it would be great to get the answers to my questions tomorrow.

Additional questions:

-The Pennsylvania Department of Environmental Protection said the EPA reached out last week to alert the department of the potential health issues. Is that right? What did the EPA share with the DEP? What prompted the EPA to contact the DEP?

-In Willowbrook, the EPA did air monitoring around the Sterigenics facility? Why there but not in the Lehigh Valley? I think emissions are comparable if not higher here.

BIng

From: Jones, Enesta <Jones.Enesta@epa.gov>

Sent: Monday, July 15, 2019 1:07:56 PM

To: Huang, Binghui

Cc: Press

Subject: Questions regarding B. Braun and ethylene oxide

EXTERNAL SOURCE

Hello Bing, my colleague from our Region 3 office forwarded your questions below. Are you working on a deadline? Also, if you have questions beyond those outlined, please let me know.

-What does the EPA plan to do after releasing NATA data that shows the increased cancer risks of ethylene oxide emissions? What are next steps?

-The EPA conducted air monitoring by Sterigenics. Does it plan to do further studies by other facilities that are major ethylene oxide emitters? Does it plan to do any monitoring or further studies by B. Braun/ in the Lehigh Valley in Pennsylvania?

-Has the EPA corresponded with B. Braun regarding ethylene oxide? I saw that the EPA wrote to Sterigenics before the release of NATA data to inform them of the dangers of the chemical. <https://www.documentcloud.org/documents/5021272-2017-12-USEPA-Letter-to-Sterigenics-on-Modeling.html>

-Was B. Braun also contacted in the past five years by the EPA regarding its ethylene oxide emissions?

-In 2016, the EPA investigated possible air and water quality issues caused by B. Braun, and found that there was no environmental issue that required clean up or action. https://www.epa.gov/sites/production/files/2016-01/documents/b_braun_medical_sb.pdf

-But in 2015, Sterigenics emitted about 7,000 pounds of ethylene oxide. I'm confused why the B. Braun report did not look at the health risk of the chemical when the same year a letter to sterigenics highlighted the cancerous risk of breathing in the chemical. What prompted the B. Braun report in 2016, and why was there no mention of the health risks of ethylene oxide?

-There's mention of an evaluation by Michael Baker of B. Braun in 2011. Could you share that with me?

-By EPA's standard, a cancer risk of more than 100 in 1 million is the standard where the agency would target emitters. In the latest NATA data, almost 64,000 people in census tracts where the risk is higher than 100 in 1 million. What does that mean for the EPA? Will there be follow up?